UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND **POLLUTION PREVENTION**

MEMORANDUM

Date: September 7, 2018

Alpha-cypermethrin: Review of Developmental neurotoxicity screening study in **SUBJECT:**

Wistar rats - Oral administration of the dams and pups (gavage)

PC Code: 109702, 209600 **DP Barcode:** D446942 **Decision No.:** 540740 Registration No.: Multiple

Regulatory Action: Registration Review **Petition No.:** N/A

Case No.: 7464 Risk Assessment Type: Single-chemical

aggregate

TXR No.: 0057776 CAS No.: 52315-07-8, 67375-30-8

MRID No.: 50572801 **40 CFR:** §180.418

FROM: Krystle Yozzo, Ph.D., Biologist

Risk Assessment Branch II (RABII) Health Effects Division (7509P)

THROUGH: Christina Swartz, Branch Chief

Risk Assessment Branch II (RABII) Health Effects Division (7509P)

TO: Susan Bartow, Chemical Review Manager

Linda Arrington, Branch Chief

Risk Management and Implementation Branch IV

Pesticide Re-Evaluation Division (7508P)

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CONCLUSIONS: The Health Effects Division's (HED) Risk Assessment Branch II I. (RABII) reviewed the study "Developmental neurotoxicity screening study in Wistar rats - Oral administration of the dams and pups (gavage)" (MRID 50572801). The study was not useful for risk assessment purposes.

- II. ACTION REQUESTED: RABII was asked to review the study "Developmental neurotoxicity screening study in Wistar rats Oral administration of the dams and pups (gavage)" (MRID 50572801).
- III. BACKGROUND: BASF met via conference call with the Agency on March 29, 2018. During this call, BASF informed the Agency of the existence of a non-guideline developmental neurotoxicity (DNT) study conducted by BASF's European affiliate (Developmental neurotoxicity screening study in Wistar rats Oral administration of the dams and pups [gavage] [MRID 50572801]). The study design differs from the Agency's guideline DNT study; however, BASF submitted the study for the Agency's records.
- IV. RESULTS/DISCUSSION: RABII screened the study "Developmental neurotoxicity screening study in Wistar rats Oral administration of the dams and pups (gavage)" (MRID 50572801) The study is not useful for human health risk assessment, and therefore a data evaluation record (DER) has not been completed. The vehicle used in the study is carboxymethylcellulose (CMC) suspension in drinking water. CMC has been found to decrease the absorption rate and lessen the potency and toxicity of pyrethroid compounds. Furthermore, concerns regarding studies on pyrethroid compounds that used CMC as a vehicle are discussed in the published literature and further emphasized in an EPA report released in a July 18, 2007 draft document "assessing approaches for the development of PBPK models for pyrethroid pesticides". Therefore, the results of this study cannot be used to inform the hazard characterization for the cypermethrins, and cannot be compared to other studies in the toxicology database.

¹ https://archive.epa.gov/scipoly/sap/meetings/web/pdf/pyrethroidpbpk sap 2007 finalv1.pdf